- TAB 10 FDA Reviewer's Literature Survey to Determine Correlation of Infection Rates to Microbiological Endpoints:
 - Healthcare Personnel Handwashes Colleen Rogers, Ph.D.
 - Surgical Hand Scrubs Michelle M. Jackson, Ph.D.
 - Patient Preoperative Skin Preparations Peter Kim, M.D.



HEALTHCARE ANTISEPTIC DRUG PRODUCTS REVIEW

Food and Drugs Administration Center For Drug Evaluation and Research Division of Over-the-Counter Drug Products (HFD-560)

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PHARMACOLOGICAL CATEGORY:

Healthcare Antiseptic Drug Products:

Surgical Hand Scrub

REVIEWER:

Michelle M. Jackson, Ph.D.

Purpose:

In the preparation for the meeting with the Nonprescription Drugs Advisory Committee (NDAC) meeting on March 23, 2005, reviewers of the Healthcare Antiseptic Working Group conducted a literature search to determine if there were any direct link between bacterial log reduction and decreased hospital infection rates pertaining to the use of surgical hand scrubs. Articles pertaining to surgical hand scrubs were first selected from the "Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force." Articles published between 1974 and February 2004 using eight databases (PUBMED, IPA, EMBASE, CINAHL, DIALOGSELECT, BIOSIS, PASCAL, & SCISEARCH) were selected for review. The literature search terms for surgical hand scrub articles included the following: "surgical scrub." "antiseptic," "antimicrobial," "antibacterial," "efficacy," "clinical trials," "operating room," "handwashing," "hand scrubbing," "infection," "disinfection," "antiseptic," "log reductions." "povidone iodine," "alcohol," "ethanol," "chlorhexidine gluconate," "triclosan," and "chloroxylenol." The reviewers screened over 300 articles (Appendix I) in order to put together a meta-analysis. However, the reviewers were unable to perform a meta-analysis on the correlation of infection rates to microbiologic endpoints for surgical hand scrubs due to inadequate information and variability of the study designs. This review represents a literature summary on several references found that may have some association to clinical benefit in the reduction of microbial counts on the skin obtained with surgical hand scrubs.

Background:

The purpose of surgical hand scrub is to remove transient bacteria, to reduce the resident flora, inhibit rapid rebound growth of bacteria, minimize regrowth of bacteria for the length of the procedure, or as long as possible, and to reduce the number of bacteria on hands and reduce

contamination of the operative site by recognized or unrecognized breaks in surgical gloves. Postoperative wound infections involving flora from the surgeon's hands where perforations and tears from the gloves do occur. However, most infections can be attributed to endogenous organisms from the patient, either a breach of sterile technique, inadequate preparation of the skin, or inadequate antibiotic prophylaxis.

In the FEDERAL REGISTER of June 17, 1994, FDA published an amendment to the tentative final monograph (TFM) for over-the-counter (OTC) healthcare antiseptic drug products (59 FR 31402) for professional use. The proposed rule defined performance expectation for surgical hand scrub as an antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin; it is broad spectrum, fast acting, and persistent. The surgical hand scrub indicated use is significantly reduces the number of microorganisms on the skin prior to surgery. In order for an antiseptic ingredient to be generally recognized as effective for use as a surgical hand scrub, it must have existing data from well designed clinical studies demonstrating effectiveness. FDA has proposed specific criteria for final formulation of surgical hand scrubs that are based on the recommendations of the Panel and FDA experience in evaluating the effectiveness of this type of drug product approved through the new drug approval process. The 1994 TFM proposed the following criteria for surgical hand scrubs:

19	94 TFM Current Reductio	ns
Day 1, Wash 1	Day 2*, Wash 2	Day 5*, Wash 11
1 log ₁₀ in 1 min AND bacterial count does not exceed baseline within 6 hours on day 1	2 log ₁₀ in 1 min	3 log ₁₀ in 1 min

^{*} Sampling is taken on the second day and fifth day to demonstrate the substantive activity of antimicrobial products.

Literature Review

Boyce, JM, Potter-Bynoe, G, Opal, SM, Dziobek, L, and Medeiros AA. "A common-source outbreak of *Staphylococcus epidermidis* infections among patients undergoing cardiac surgery." J Infect Dis. 1990 (161):493-9.

This article reported a common-source outbreak of infections related to cardiac surgery that was traced to colonization of a surgeon's hand by a strain of *Staphylococcus* epidermidis.

DESIGN & METHODS: This single strain of *S. epidermidis* caused an outbreak of postoperative wound infections and endocarditis during a 6-month period. Infections caused by the epidemic strain developed more frequently in valve surgery patients than in those undergoing coronary artery bypass graft surgery (P = .03) and occurred only in patients operated on by surgeon A. None of 17 members of the cardiac surgery team carried the epidemic strain in their anterior nares, axillae, or inguinal folds. Hand cultures were performed on 8 surgical personnel, and only surgeon A carried the

epidemic strain on his hands. Isolates from cardiac surgery patients, bypass pump blood cultures, and the hands of the implicated surgeon all had identical antimicrobial susceptibility patterns, plasmid profiles, and EcoRI restriction endonuclease digest patterns.

RESULTS: The investigation revealed that surgeon A had been using a nonantimicrobial preparation for scrubbing his hands for several years because he had previously developed a dermatitis attributed to an antimicrobial scrub solution. Surgeon A recently adopted the practice of applying sterile mineral oil to his hands before donning on gloves at the time of surgery. Surgeon A was not allowed to perform cardiac surgery until the epidemic strain was eradicated from his hands. He was required to use an antimicrobial scrub solution containing chlorhexidine daily for 2 weeks. Sampling was taken after scrubbing and after he had been gloved for 3-4 hours.

Reviewer's comments: What the study shows, despite its deficiencies is that there was an eradication of S. epidermidis from the surgical field 24 months after implementation of the infection control measures. The findings suggest that the common-source outbreak of infections among cardiac surgery patients was due to carriage of a strain S. epidermidis on the hands of a cardiac surgeon. The epidemic strain may come from a variety of other sources: endogenous flora of the patient, members of the cardiac team and technicians, surgical equipment, suction pump, operating room air, blood or other fluids, contaminated prosthetic valves, contaminated disinfectants, etc...The mechanism by which Surgeon A contaminated the operative field was not determined. Surgeon A was advised not to add mineral oil to his hands. Since the epidemic strain was isolated from blood cultures after the surgery, it was concluded that contamination may have resulted from glove tears during the surgery. However, this was not documented. Other factors that may have been responsible for the sudden increase in infections caused by the epidemic strain were also not determined. Further, details about the use of chlorhexidine gluconate as a surgical hand scrub were not provided. It is also not clear what if any infection control measures for other staff were instituted. This article basically shows that use of an antimicrobial scrub solution reduces the amount of colonizing S. epidermidis from the hands.

Bryce, EA, Spence, D, and Roberts, F. "An in-use evaluation of an alcohol-based pre-surgical hand disinfectant." Infect Control Hosp Epidemiol 2001 (22):635-639.

The objective of this study was to determine whether alcohol hand disinfection is an effective alternative to traditional agents for the pre-surgical scrub.

DESIGN & METHODS: A prospective clinical trial of a 70% isopropanol pre-surgical hand disinfectant Manorapid (antiseptic product) involving the operating room suites at two hospital sites in British Columbia. The cases were selected to evaluate both short and longer procedures. The hand disinfectant was compared to agents in current use as surgical scrubs (4% chlorhexidine and 7.5% povidone-iodine). Surgical technique and glove use were not modified. Surgical personnel scrubbed (using traditional solutions and brushes) for 3 minutes after cleaning under the fingernails with a nail pick, according to operating room guidelines. The alcohol hand antiseptic was used as follows: hands were washed with a mild neutral soap for 1 minute prior to the first case of the day, hands

were dried, and approximately 5 mL of the alcohol product was dispensed into a cupped hand. Staff were instructed to dip their opposing fingernails into the solution, then transfer the Manorapid to the other hand and do the same to the other fingernails; the remaining product was used to rub all areas of the hands to the wrist. A second 5 mL of solution was dispensed and the liquid dispersed up both arms to the elbows and rubbed into the skin. A third 5 mL of product then was rubbed into the hands. Total time for the surgical hand rub was approximately 3 minutes. Pre- and postoperative fingertip impression and "glove-juice" cultures were used to determine microbial burden, and hands were evaluated for skin integrity.

RESULTS: There was no statistical difference between the microbial hand counts following use of the alcohol-based product or the current agents, for cases less than 2 hours' duration. Comparison of longer surgical cases revealed significantly better preand postoperative culture results with the alcohol hand rinse, but analysis of matched pairs showed no significant difference in microbial counts. The alcohol hand rinse was equivalent to the operative scrub in terms of skin integrity and user acceptability.

Reviewer's comments: The authors concluded that an alcohol hand rinse was equivalently effective in reducing microbial hand counts as the traditional pre-surgical scrub, both immediately after hand disinfection and at the end of the surgical procedure. There were several deficiencies in the study. Demographics and disposition of the subjects were not provided. Many variables (factors) in the studies, such as glove type, glove liners, other skin agent use, and use of antibiotics and oral contraceptives (causes an adverse effect on the microbial flora of the skin) were uncontrolled. There was no washout between treatment periods. The washout period is important because subjects crossed over from more persistent antimicrobials to the alcohol. The participants were given no specific instructions regarding their use of antimicrobial-containing products such as deodorants, shampoos, lotions, or soaps, nor were they provided with kits containing non-antimicrobial personal-care products for use during the evaluation. Overall, the information gathered from this study just showed that alcohol-based product was a comparable agent to those that were currently in use and effective if used according to recommendations. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Cremieux, A, Reverdy, ME, Pons, JL, Savage, C, Chevalier, J, Fleurette, J, Mosse, M. Standardized method for evaluation of hand disinfection by surgical scrub formulations. Appl Envirn Microbiol 1989;55:2944-2948.

The objective of the study was to assess the validity of a protocol on the basis of statistical analysis and to compare the two antiseptic scrub formulations (povidone iodine (PVI) and chlorhexidine (CHX)) with each other and with the nonmedicated soap (NMS). A standardized protocol for the evaluation of hand disinfection by surgical scrub formulations was applied to volunteers in a multicenter trial.

METHODS: Adult volunteers were gathered for each of the three studies (PVI, CHX, and NMS) in seven groups corresponding to distinct centers. All centers were involved

in the PVI study (49 subjects, seven groups of 10, 6, 8, 6, 10, 6, and 3 subjects), while one center was missing for the NMS study (41 subjects, six groups of 10, 6, 7, 6, 6, and 6 subjects) and two centers were missing for the CHX study (35 subjects, five groups of 10, 6, 8, 8, and 3 subjects). All subjects were instructed to avoid the use of antiseptics. detergents, and gloves during the experiment. Subjects were not prescreened for an adequate baseline count. The scrubbing procedure involved three daily hand washings occurring on day 2-4; surviving bacteria were counted daily after being collected in a suitable neutralizing solution. Immediate efficacy (IE), cumulative efficacy (CE), and remanent effect (RE) were calculated by reference to the control hand. Hand flora was recovered in a sterile plastic bag containing 400 ml of a neutralizing solution which has previously been demonstrated as convenient for the two scrub formulations and the soap. Five minutes after the end of the scrubbing procedure, the appropriate hand (left hand for control counts and right hand for test formulation) was plunged into the bag and agitated for 5 minutes. The solution was then transferred into a sterile bottle. Samples were placed in 15 ml tryptic soy agar. Colonies were counted after 48 hours of aerobic incubation at 37°C. All counts were conducted in duplicate.

RESULTS: Statistical analyses of IE, CE and RE showed significant differences among the three scrub formulations. IEs of PVI and CHX were equivalent and different from IE of NMS; CE and RE of CHX were higher than those of PVI and NMS. Statistical analysis was limited to IE on day 1, CE on day 5 and RE on day 8.

TABLE 2. Results of IE, CE, and RE with three scrub formulations for one group (10 subjects)

Day	Scrub formulation	Control (C1" or Cd")	Test (T1° or Td*)	IE (C) - T1; Cd - Td)	(CI ~ Td)	(C1 ~ Cd)
1	PVI	6.48 ± 0.98°	5.78 ± 1.07	0.70 ± 0.79		
	CHX	6.51 ± 0.58	5.75 ± 0.69	0.76 ± 0.53		
	NMS	6.58 ± 0.58	6.01 ± 0.75	0.57 ± 0.23		
2	PVI	5.69 ± 1.01	5.22 ± 0.81	0.47 ± 0.51	1.26 ± 0.62	0.80 ± 0.28
	CHX	5.44 ± 0.46	4.76 ± 0.54	0.68 ± 0.49	1.75 ± 0.48	1.08 ± 0.50
	NMS	6.23 ± 0.51	5.93 ± 0.41	0.30 ± 0.32	0.65 ± 0.41	0.35 ± 0.45
3	PVI	5.47 ± 0.59	4.95 ± 0.79	0.52 ± 0.58	1.53 ± 0.86	1.01 ± 0.71
	CHX	4.93 # 0.82	3.66 ± 1.36	1.27 ± 1.19	2.85 ± 1.08	1.58 ± 0.79
	NMS	6.21 ± 0.40	5.86 ± 0.67	0.35 ± 0.48	0.72 ± 0.69	0.37 ± 0.52
4	PVI	5.09 ± 1.03	4.59 ± 0.75	0.50 ± 0.73	1.89 ± 0.78	1.40 ± 0.54
	CHX	5.12 ± 0.76	3.38 ± 1.44	1.75 ± 1.24	3.13 ± 1.22	1.39 ± 0.64
	NMS	6.29 ± 0.39	5.88 ± 0.39	0.41 ± 0.20	0.70 ± 0.45	0.29 ± 0.57
5	PVI	5.50 ± 0.78	5.10 ± 0.77	0.40 ± 0.42	1.39 ± 1.03	0.98 ± 0.97
	CHX	5.06 ± 0.57	4.12 ± 0.45	0.95 ± 0.51	2.39 ± 0.58	1.45 ± 0.61
	NMS	6.31 ± 0.31	5.81 ± 0.66	0.51 ± 0.42	0.77 ± 0.41	0.27 ± 0.47
8	PVI	6.36 ± 0.60	5.63 ± 1.13	0.92 ± 0.76	0.85 ± 1.04	-0.08 ± 0.83
	CHX	6.02 ± 0.38	4.50 ± 0.79	1.53 ± 0.92	2.02 ± 0.86	0.49 ± 0.52
	NMS	6.59 ± 0.42	6.05 ± 0.48	0.54 ± 0.28	0.53 ± 0.43	-0.01 ± 0.56

C1, Count obtained on day 1 with the control hand (base line count).
Cd. Count obtained from day 2 to day 8 with the control hand.
T1, Count obtained on day 1 with the test hand.
Td, Count obtained from day 2 to day 8 with the test hand.

TABLE 4. IE, CE, and RE of PVI, CHX, and NMS and comparison by Student's t test"

Scrub formulation and comparison	No. of subjects	IE (day 1)	CE (day 5)	RE (day 5)	RE (day 8)
PVI	49	0.94 ± 0.57	1.67 ± 0.78	0.99 ± 0.76	0.20 ± 0.74
CHX NMS	35 41	1.08 ± 0.57 0.62 ± 0.36	2.42 ± 0.81 0.78 ± 0.55	1.33 ± 0.62 0.39 ± 0.55	0.45 ± 0.58
NMS < PVI ^b	7,	0.002	0.000	0.39 2. 0.33	0.06 ± 0.49 0.281
$NMS < CHX^b$ $PVI < CHX^b$		0.000 0.251	0.000 0.000	0.000 0.024	0.008 0.077

Values are means ± standard deviation.

Mean ± standard deviation of log₁₀ number of microorganisms per band

b Student's t test.

Reviewer's Comments: This article mainly focused on describing a standardized method for evaluation of hand disinfection by various surgical scrub formulations. The aim of the study was to assess the validity of the protocol on the basis of statistical analysis and to compare the two antiseptic scrub formulations with each other and with the nonmedicated soap. The authors concluded that the protocol described may be considered satisfactory for the comparison of scrub formulations because it allows comparisons between ineffective, bactericidal, and bactericidal plus remanent scrubs. Their analyses of data indicate that the population size required for further studies aimed at detecting significant differences between surgical scrub formulations could be estimated. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. The data were generated from nonrandomized, uncontrolled, and unblinded study. Demographics and disposition of the subjects were not provided (ratio of males to females and ages not described). The study does not describe the baseline determination. Normally baseline counts are performed in triplicate (days 1, 3, and 5) using a nonantimicrobial soap. The baseline count of the resident microbial populations is performed to evaluate eligibility of the study, as well as establish baseline values for each subject. Normally those subjects with baseline counts of at least 1.5 x 10^5 organisms per hand are selected to continue the study. This article mentions that the mechanical effect of repeated scrubbing and bactericidal effect of the antiseptics differentially reduced hand flora, but the study was limited to a quantitative evaluation of the bacteria. Overall, there was no information regarding the correlation of infection rates to the reduction of bacteria and no clinical outcome data.

Grinbaum, RS, de Mendonca, JS, Cardo, DM. "An outbreak of handscrubbing-related surgical site infections in vascular surgical procedures." Infect Control Hosp Epidemiol 1995;16:198-202.

The objective of the study reported in this publication was to investigate an outbreak of surgical site infections in vascular surgery unit related to handscrubbing with non-antimicrobial soap.

DESIGNS & METHODS: A 60-bed unit of vascular surgery, where surgeons performed an average of 30 operations per month at a 1,000-bed tertiary care hospital in Sao Paulo, Brazil. The study included in the case group nine patients who had limb amputations or arterial reconstructions from October 16 through 23, 1992. The study included in the control group patients (two controls for each case) whose operations were performed within 30 days of the outbreak period. Control patients were matched for sex and type of operation.

RESULTS: Six of nine case patients experienced surgical site infection, as compared with 3 of 18 control patients (P=0.026) and 28 of 244 patients in the pre-epidemic period (P=0.0002). The risk factors were balanced for case and control groups. Factors assessed were American Society of Anesthesiology status, duration of surgery, wound class, emergency status, remote site infections, preoperative length of stay, use of prophylactic antibiotics, and underlying diseases. Possible common sources also were analyzed. No differences were observed concerning hair removal, preoperative shower, wound dressing, and surgical team present in the operating room.

During the outbreak period, the operating room was not provided with povidone-iodine, used in the hospital for skin cleansing and handscrubbing. Surgeons from all departments, including vascular surgery, used 2% iodine with 70% alcohol for skin cleansing. Surgeons from other departments used this iodine solution for hand scrubbing, but the vascular surgeons used plain soap for handscrubbing. No increases in surgical site infection rates were reported in other services. Comparison of case and control groups for handscrubbing was statistically significant (P<0.0001). After reinstitution of povidone-iodine, only one surgical site infection was diagnosed in 13 vascular procedures. Overall, the conclusions drawn by the authors based on their analyses of data indicate that they could not demonstrate definitely that scrubbing with plain soap was related to surgical site infections, but they found a strong suggestion of this association.

Reviewer's comments: Because of numerous deficiencies, the data presented is not able to demonstrate definitely that scrubbing with plain soap was related to surgical site infections. There were difficulties in the design of a case-control study in this outbreak because a small number of operations were studied and all patients were exposed to the suspected risk factor. Because of the unblinded nature of the study, bias cannot be ruled out. There was no description of the surgical hand scrubbing procedure that was used in the hospital. (how long the hands were scrubbed and how they were scrubbed). There were other risk factors to take in for consideration such as the presence of a particular surgeon, aseptic techniques, sterilization techniques, type of wound dressing applied etc... Overall, there was no valuable information regarding the correlation of infection rates to the reduction of bacteria.

Herruzo-Cabrera, R, Vizcaino-Alcide, MJ, and Fdez-Acinero, MJ. "Usefulness of an alcohol solution of n-duopropenide for the surgical antisepsis of the hands compared with handwashing with iodine-povidone and chlohexidine: clinical essay." J Surg Res 2000 (94):6-12.

The objective of this study was to compare four alcohol solutions with the classic surgical handwashing products (chlorhexidine and iodine-povidone), in both *in vitro* and *in vivo* studies. The study was conducted to show that the usual surgical antisepsis involves scrubbing the skin with antiseptic solutions and this procedure can damage the skin, with the subsequent risk of infection for the patient. The authors discuss several efficient and quick-acting antiseptic alcohol solutions that require no scrubbing.

DESIGN & METHODS: Four alcohol solutions were compared with the classic surgical handwashing products (chlorhexidine and iodine-povidone), in both *in vitro* (pigskin germ carriers) and *in vivo* studies. *In vitro* studies were performed on lyophilized pig skin, cut in circles 0.5 cm in diameter, sterilized in steam flow, introduced into the culture medium with the tested germ, and left to grow on and between the skin trabeculae. Neutralizers were used and samples were taken and plated onto TBS agar. Multiresistant microorganisms were used. *In vivo* studies (clinical essays) were done with 15 healthy volunteers (crossed design) as well as with 154 surgical team members, whose hand microbial flora were measured before and after scrubbing up and after surgery.

RESULTS: Due to the efficiency in the germ carrier, N-duopropenide in 60% alcohol with emollients was chosen for further comparison with the standard surgical scrub: 4% chlorhexidine and 7.5% iodine-povidone. The quantitative, semi-quantitative, and qualitative results obtained with N-duopropenide without scrubbing were better in the healthy volunteers and surgical teams. This product reduced hand microorganisms by more than 2-log, and maintained the reduction for the entire study period. Four percent chlorhexidine initially reduced colonization more than 2-log but lost part of its effect over time during the surgical intervention. 7.5% iodine-povidone reduced the germs by 1 log but at the end of surgery there were even more germs than before washing.

Reviewer's comments: The authors concluded that scrubbing with classic antiseptic solutions should be replaced with gentle washing with an alcohol solution such as N-duopropenide in alcohol because of its efficacy, persistent effect, and skin protection. However, the study contains the following deficiencies: Demographics and disposition of the volunteers and surgical teams were not provided. No description of history of skin disease and whose hands were free of cuts, abrasions and disease. No description of whether the subjects were on antibiotics and/or oral contraceptives (causes an adverse effect on the microbial flora of the skin). The study was not blinded. No description of washout period. No description of scrub technique that was used. Overall, the information gathered from this study focused mainly on promoting the use of N-duopropenide in alcohol. The study was not designed to demonstrate a correlation between infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Larson, EL, Butz, AM, Gullette, DL, Laughon, BA. "Alcohol for surgical scrubbing?" Infect Control Hosp Epidemiol 1990 (11):139-143.

The purpose of the study was to compare the immediate and sustained antimicrobial effectiveness and user acceptability of surgical scrub preparations containing either alcohol, triclosan, chlorhexdine gluconate or povidone iodine.

DESIGN & METHODS: Sixty healthy adult volunteers was selected who were not receiving systemic or topical antibiotics and who reported no history of skin disease or sensitivity to soaps. The subjects were assigned by block randomization (12 subjects per group) to use one of the following formulations: 70% ethyl alcohol with 0.5% chlorhexidine gluconate (ALC); a liquid detergent base containing 1% triclosan(TRI); a liquid detergent base containing 4% chlorhexidine gluconate (CHG); a liquid detergent base containing 7.5% povidone-iodine (PI); or a nonantimicrobial liquid soap (control). Using standard scrub protocol (ASTM method), subjects performed 5-minute surgical scrub daily for five consecutive days. Hand cultures were obtained at baseline and on test days 1 and 5 immediately after the scrub and following four hours of gloving.

RESULTS: After the first and last scrubs, ALC, CHG and PI resulted in significant reductions in colonizing flora when compared to the control. Additionally, by day 5 ALC was associated with an almost 3-log reduction as compared to an approximate 1.5-log reduction for CHG and PI and less than a 1-log reduction for TRI and the control (p = .009). After 4 hours of gloving on both days 1 and 5, microbial counts on hands of

subjects using ALC, TRI and CHG were significantly lower than counts for the control (p less than .001), whereas there was no significant difference in counts between the PI and control groups (p = .41). None of the test products exceeded baseline on days 1 and 5. Skin assessment by study subjects rated products from least to most harsh as follows: control, TRI, CHG, ALC and PI p = .00001).

Mean Log Count (+ Standard Deviation) From Hands of 60 Subjects Using Surgical Scrub Protocol						
Active Ingredient	Baseline	After Scrub 1	After 4 hrs	After Scrub 5	After 4 hrs	
			Gloving Day 1		Gloving Day 5	
Alcohol	6.04	4.06	4.83	3.19	3.62	
	(0.49)	(1.20)	(1.10)	(0.72)	(1.34)	
Triclosan	5.84	5.28	5.39	5.28	5.69	
	(0.67)	(0.58)	(0.96)	(0.54)	(0.44)	
Chlorhexidine	5.80	4.94	5.21	4.24	4.04	
	(0.58)	(0.95)	(1.10)	(0.63)	(1.11)	
Povidone-Iodine	6.18	5.10	5.91	4.61	5.68	
	(0.39)	(0.47)	(0.46)	(0.49)	(0.31)	
Control	6.07	5.68	6.06	5.65	6.29	
	(0.57)	(0.42)	(0.47)	(0.46)	(0.51)	
ANOVA 5 groups	F:104	6.89	4.13	32.9	23.3	
	p .39	<.001	<.001	<.0001	<.0001	

Reviewer's comment: The authors concluded that alcohol could be an efficacious and acceptable alternative for surgical scrubbing. There were numerous deficiencies in the studies. There was limited description regarding the use of neutralizers in the samples. No description about neutralization validation was provided. Subjects using oral contraceptives (causes an adverse effect on the microbial flora of the skin) were not excluded. Demographics and disposition of the participants were not provided. The study was not blinded. The study contained a small sample size of subjects. Only a 3-day washout period was conducted. Only a single baseline count was determined in the study. Normally baseline counts are performed in triplicates (days 1, 3, and 5) using a non-antimicrobial soap. The baseline count of the resident microbial populations is performed to evaluate eligibility of the study, as well as establish baseline values for each subject. Normally those subjects with baseline counts of at least 1.5 x 10⁵ organisms per hand are selected to continue the study. Hand sampling was not randomized. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Maki DG. "The use of antiseptics for handwashing by medical personnel." Chemother 1989 (1):3-11.

This review article describes various studies that have shown that the major reservoir of nosocomial infection in the hospital is the infected or colonised patient and the major mode of spread of organisms between patients is on the hands of medical personnel.

Hygienic handwashing in the hospital or clinic, to remove transient contaminants acquired from patients or the environment and prevent cross-infection to vulnerable patients, is similarly regarded as one of the most fundamental infection control measures, yet is done infrequently by personnel in most hospitals. Following a typical brief (7.10

second) handwashing with a nonmedicated soap, the number of organisms that can be transmitted from the person's hands may, paradoxically, actually increase. Use of chlorhexidine for handwashing or application of an evaporative alcohol-based lotion has been found to reduce shedding of bacteria-laden skin squames. Routine use of antiseptic-containing handwashing agents is clearly more effective than nonmedicated soaps for microbial removal, enhancing the value of the handwashings and possibly protecting against contaminants acquired between handwashings. In a sequential comparative trial of three handwashing agents in a surgical intensive care unit--a nonmedicated soap, 10% povidone-iodine solution, and 4% aqueous chlorhexidine, each used exclusively for approximately six weeks the incidence of nosocomial infection was 50% lower during the use of the antiseptic handwashing products than during the use of nonmedicated soap (P less than .001). Novel approaches are needed to improve the frequency of hygienic handwashing.

Reviewer's comment: The author concludes that the advances in hand degerming could substantially reduce the incidence of nosocomial infection. This article gives a historical review on various handwashing studies. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Morrison, AJ, Gratz, J, Cabezudo, I, Wenzel, R. "The efficacy of several new handwashing agents for removing non-transient bacterial flora from hands." Infect Control 1986 (7):268-72.

This article describes several new handwash agents for efficacy in removing non-transient flora from the hands of medical personnel using the sterile bag technique of quantitative hand culture after brief contact times, while incorporating an effective handwash agent neutralizer.

DESIGN & METHODS: Forty subjects participated in a study of six handwashing agents evaluated for their efficacy in removing non-transient bacteria: 70% isopropanol, 0.05% stabilized iodine, 4% chlorhexidine gluconate, 1% para-chloro-meta-xylenol, 0.5% chlorohexidine gluconate, and 60% isopropyl alcohol with emollients. Phase one of the study involved each subject using a non-medicated handwash to remove transient flora. Afterwards, three consecutive experimental handwashes were performed using a 10-second contact time, and a fourth handwash employed a 1-minute contact time. Quantitative post-handwash cultures were obtained using the sterile bag technique incorporating an effective agent neutralizer. Phase two of the study involved obtaining subject's baseline bacterial flora. Then four consecutive agent applications were performed. Hand culturing was performed between each agent application using a sterile bag technique. After culturing, a tapwater rinse without friction was performed to eliminate residual broth, and then the hands were air-dried without friction prior to the next application of agent.

RESULTS: Significant mean log10 reductions were documented for chlorhexidine gluconate, but only after the third (P = .05) and fourth (p = .004) handwash. However, the total log10 reduction was less than 1.0 for any single agent. Subsequently, three evaporative handwash agents, including 70% isopropanol, 0.5% chlorhexidine in 70%

isopropanol, and a 60% isopropanol formulation containing evaporative retardants, were tested in 14 subjects. Contact time was prolonged to the point of evaporation prior to culturing. Four consecutive post-handwash cultures were obtained after performing a baseline pre-handwash culture. When compared with the other two evaporative agents, the 60% isopropanol formulation demonstrated significant mean $\log 10$ reductions for each handwash (p less than or equal to .03), with a total $\log 10$ reduction of 2.9 over all four handwashes (p = .0001).

Table 1. Inter-agent comparisons of mean \log_{10} bacterial reduction / mean after each of four consecutive handwashes with four handwashing agents (N=40)

Handwash Number	MLR IA	MLR AK	MLR IK	MLR HC
1	0.05	0.15	0.12	0.19
2	0.17	0.23	0.12	0.21
3	0.07	0.11	0.08	0.25*
4	0.04	0.14	0.06	0.29†
Total (1-4)	0.33	0.63	0.38	0.94‡

^{*}p=0.05; HC more efficacious than IA/AK/IK

Key:

IA=70% isopropyl alcohol with 1% glycerin

AK=Acute-Kare; 1% PCMX; Calgon Corporation, St.Louis, MO.

IK=Ido-Kare; 0.05% stabilized iodine; Calgon Corporation, St. Louis, MO.

HC=Hibiclens; 4% Cholorhexidine gluconate; Stuart Pharmaceuticals

Table 2. Inter-agent comparisons of mean log_{10} bacterial reduction (MLR) after each of four consecutive handwashes with three evaporative handwashing agents (N=14)

Handwash	MLR	MLR	MLR
Number	IA	HS	CS
1	-0.5	- 0.15	1.4*
2	0.3	0.0	0.5†
3	0.0	0.1	0.5
4	0.2	0.0	0.5**
Total (1-4)	0.0	-0.3	2.9††

^{*}p=0.0001; CS more efficacious than IA/HS

Key:

IA=70% isopropyl alcohol with 1% glycerin

HS=0.5% chlorhexidine gluconate in 70% isopropyl alcohol; Stuar Pharmaceuticals, Wilmington, DE

CS=60% isopropyl alcohol with evaporative retardants; Calgon Corporation, St. Louis, MO

HC=Hibiclens; 4% Cholorhexidine gluconate; Stuart Pharmaceuticals

[†]p=0.004; HC more efficacious than IA/AK/IK

[‡]p=0.0001; HC more efficacious than IA/AK/IK

[†]p=0.02; CS more efficacious than IA/HS

[‡]p=0.03; CS more efficacious than IA/HC

^{**}p=0.0001; CS more efficacious than IA/HC

Reviewer's comment: The authors concluded that data from this study do not imply any agent preference for the reduction of non-transient flora with the possible exception of 60% isopropyl alcohol. The authors also suggest that further studies are needed to substantiate the importance of non-transient bacteria in nosocomial infections. No description of the type of neutralizers that were used. No description of washout period was conducted. There were no demographics and disposition of the subjects provided. The study contained a small sample size of subjects. There was no mention of the exclusion criteria of subjects admitted into the study including use of topical or systemic antimicrobials, or any other medication (such as oral contraceptives) known to affect the normal flora of the skin. There was no blinding of test formulations. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

O'Farrell, DA, Kenny, G, O'Sullivan, M, Nicholson, P, Stephens, M, and Hone, R. "Evalution of the optimal hand-scrub duration prior to total hip arthroplasty." J Hosp Infect 1994 (26):93-98.

This objective of this study was to re-assess the antimicrobial efficacy of two different scrub durations that are applicable to orthopaedic practice in view of the increased use of power instrumentation and manual exertion.

DESIGN & METHODS: The study evaluated the antimicrobial efficacy of a 5 min compared with a 10 min scrub before both long (> 90 min) and short (< 90 min) operations for total hip arthroplasty. Orthopaedic surgeons in many major arthroplasty centers advocate the use of a prolonged surgical hand-scrub prior to total joint replacement. Surgical hand disinfection was performed on one occasion for 5 min and on a second for 10 min by 41 surgeons and theatre nurses using 4% chlorhexidine gluconate as a detergent formulation ('Hibiscrub', ICI Pharmaceuticals). None of the subjects had previously scrubbed on the day of each test. Bacterial colony counts on the fingers were measured using the method described by Rotter (vide infra) before scrubbing, immediately after scrubbing, and at the end of each operation.

RESULTS: The results showed that for arthroplasty procedures lasting less than 90 min (35 operations), a 5 min hand-scrub was equally as effective as one of 10 min. However, following longer procedures (36 operations) colony counts were significantly higher on subjects who had scrubbed for 10 min than on those who only scrubbed for 5 (P < 0.05, Mann-Whitney U-Test).

Reviewer's comments: The authors suggest that the practice of a prolonged scrub before total joint replacement does not have a scientific basis and that such a policy should be discontinued where it is still practiced. The study was not a clinical trial designed study. There were 13 glove perforations found in 82 operations, 9 of which occurred in operations under 90 min and 4 in operations over 90 min in duration. There was no mention if there were any surgical site infections. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria.

Parienti JJ, Thibon P, Heller R, LeRoux Y, von Theobald P, Bensadoun H, Bouvet A, Lemarchand F, Le Coutour X. "Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates." JAMA 2002 (288):722-727.

The purpose of this study was to compare the effectiveness of hand-cleansing protocols in preventing surgical site infections during routine surgical practice.

DESIGNS & METHODS: Randomized equivalence trial comparing hand-scrubbing and hand-rubbing protocols with a multiple service crossover experimental design. Six surgical services from teaching and nonteaching hospitals in France included a total of 4387 consecutive patients who underwent clean and clean-contaminated surgery between January 1, 2000, and May 1, 2001. Surgical services used 2 hand-cleansing methods alternately every other month: a hand-rubbing protocol with 75% aqueous alcoholic solution containing propanol-1, propanol-2, and mecetronium etilsulfate; and a hand-scrubbing protocol with antiseptic preparation containing 4% povidone iodine or 4% chlorhexidine gluconate. Thirty-day surgical site infection rates were the primary end point; operating department teams' tolerance of and compliance with hand antisepsis were secondary end points. A non-medicated soap was used in conjunction with the first wash of the day and also when the hands were visibly soiled. Surgical site infections were prospectively diagnosed by a surgeon, infectious disease specialist, or hygiene specialist on a standard data-collection form. Post-discharge surveillance was based on chart review of visits and telephone contacts with the surgeons.

RESULTS: The two protocols were comparable in regard to surgical site infection risk factors. The Table below shows that the surgical site infection rates were 55 of 2252 (2.44%) in the hand-rubbing protocol and 53 of 2135 (2.48%) in the hand-scrubbing protocol, for a difference of 0.04% (as treated 95% confidence interval, -0.88% to 0.96%). During the study period, 278 individual compliance assessments were made of the operating teams (174 in the hand-rubbing group), corresponding with 160 surgical procedures (102 in the hand-rubbing group). On the average, the first hand-cleansing protocol of the day, excluding the simple non-antiseptic hand wash prior to hand-rubbing, lasted significantly longer in the hand-rubbing group than in the hand-scrubbing group (mean [SD], 313 [80] seconds vs 287 [75] seconds; P=.01). Scrub nurses complied better with the recommended duration of hand antisepsis than did surgeons and assistants (56% vs 33%; P<.001). Based on subsets of personnel, compliance with the recommended duration of hand antisepsis was better in the hand-rubbing protocol of the study compared with the hand-scrubbing protocol (44% vs 28%, respectively; P=.008), as was tolerance, with less skin dryness and less skin irritation after aqueous solution use.

Table 2. Surgical Site Infection (SSI) Rates and Differences Between Hand-Scrubbing and Hand-Rubbing*

	No. SSI/No. O	perations (%)	SSI Rate Difference	χ² Test of Equivalence (P Value)	
Alterneier Class of Contamination	Hand-Scrubbing Protocol	Hand-Rubbing Protocol	(Hand-Scrubbing- Hand-Rubbing), % (95% Confidence Interval)		
Clean	29/1485 (1.95)	32/1520 (2.11)	-0.15 (-1.16 to 0.85)	16.0 (<.001)	
Clean-contaminated	24/650 (3.69)	23/732 (3.14)	0.55 (-1.36 to 2.46)	1.9 (.09)	
Al	53/2135 (2.48)	55/2252 (2.44)	0.04 (-0.88 to 0.96)	19.5 (<.001)	

^{*}The 96% confidence interval of the SSI rate difference was calculated according to Wallenstein¹⁵ and the χ² test was the lowest χ² value of the Dunnett and Cent¹¹ continuity corrected double 1 sided test for equivalence at −2% and +2%.

Table 3. Compliance With the Recommended Duration of Hand Antisepsis During the First Procedure of the Day*

Operating Room Personnel	Hand-Scrubbing Protocol	Hand-Rubbing Protocol	<i>P</i> Value† .01‡
Duration of hand antisepsis, mean (range), s	287 (100-480)	313 (60-510)	
No. of hand antisepsis ≥5 min/total no. of hand antisepsis (%) Surgeon/assistant	20/83 (24)	51/133 (38)	.04
Scrub nurse	9/21 (42)	26/41 (63)	.18
All	29/104 (28)	77/174 (44)	.008

^{*}Time required for the nonantiseptic hand wash prior to hand rubbing with aqueous alcoholic solution has been excluded.

Analyzed using Fisher exact test.

†Analyzed using Mann-Whitney test.

Reviewer's Comments: What the study shows, despite its deficiencies is that 75% alcoholic solution (propanol-1, propanol-2 and mecetronium etilsulfate) with PVP-I and CHG in actual surgical situations showed no statistical difference in the surgical site infection rates. This is the first randomized trial to compare hand-rubbing with alcoholbased solution with traditional hand-scrubbing in the routine surgical setting. The authors mention that according to CDC guidelines, all surgical site infections had to be confirmed by the surgeon or the physician in charge of the patient. Therefore, observers of the clinical outcome could not be blinded to the hand antisepsis protocol. Because of the unblinded nature of the study, bias cannot be ruled out. There was no description on how the patients were cared for after the operation, details on health of the patients, or antibiotics use before undergoing surgical procedures. There was no microbiological evaluation of SSI on the patients. It would be difficult to link the source of infection to the surgeon. There were no reports of glove tears or punctures. Other risk factors such as aseptic techniques, sterilization of surgical instruments used, type of wound dressing applied etc...were not considered. In conclusion, the trial does not provide absolute evidence correlating clinical outcome of infection rates to the reduction of bacteria on the surgeon's hands.

Pereira LJ, Lee GM, and Wade KJ. "The effects of surgical handwashing routines on the microbial counts of operating room nurses." Am J Infect Control 1990 (18):354-364.

The objective of the study reported in this publication was to determine whether a shorter duration surgical scrub achieves the same reductions in colony forming units (CFU) as a standard scrub.

DESIGNS & METHODS: This study examined two interdependent factors: the time taken to wash the hands and the type of antiseptic solution used. A 3-minute initial scrub and 30-second consecutive scrub regimen was compared with a current standard regimen of a 5-minute initial scrub and a 3-minute consecutive scrub. Chlorhexidine gluconate 4% and povidone-iodine 7.5% were the antiseptics used in the two regimens. The sample (n = 34) was drawn from nurses employed in the operating room suite of a 950-bed hospital.

RESULTS: Chlorhexidine gluconate was found to be responsible for lower numbers of colony-forming units of bacteria than povidone-iodine. The duration of the scrub had no significant effect on the numbers of bacteria when povidone-iodine was used. The optimal regimen was found to be the 5-minute initial and 3-minute consecutive scrubs with chlorhexidine gluconate.

Reviewer's Comments: The authors analyses of data indicate that although the shorter-duration surgical scrub is apparently adequate with either of the scrub antiseptics tested, the longer-duration surgical scrub with chlorhexidine gluconate achieves and maintains the best microbial reductions. The study did not provide any demographics and disposition of the subjects. The study contained small sample size of subjects. A washout period of one week was included but subjects were instructed to continue normal handwashing procedures during this period. There was no information regarding blinding of the test materials and those analyzing the data. There was no use of a baseline non-antimicrobial control soap. No description of neutralization validation was provided. There was a significant difference between hand counts which made it necessary to calculate predicted microbial counts. Overall, the information gathered from this study focused mainly on comparing two surgical hand disinfectants povidone iodine and chlorhexidine gluconate and the optimal scrub time. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Pereira, LJ, Lee, GM, and Wade, KJ. "An evaluation of five protocols for surgical handwashing in relation to skin condition and microbial counts." J Hosp Infect 1997 (36):49-65.

The purpose of this study was to (1) determine whether a shorter duration surgical scrub protocol with a variety of antiseptics can achieve the same reductions in microbial numbers as a more conventional (5 min duration) method with 4% CHG and (2) determine whether a reduction in the duration of the surgical scrub would result in improved skin condition assessments.

DESIGN & METHODS: Five protocols for surgical handwashing (scrubbing) were evaluated for their efficiency of removal of micro-organisms and their drying effect on the skin. The scrubbing protocols tested were: (1) an initial scrub of 5 min and consecutive scrubs of 3.5 min with chlorhexidine gluconate 4% (CHG-5); (2) an initial scrub of 3 min and consecutive scrubs of 2.5 min with chlorhexidine gluconate 4% (CHG-3); (3) an initial scrub of 3 min and consecutive scrubs of 2.5 min with povidone iodine 5% and triclosan 1% (PI-3); (4) an initial scrub of 2 min with chlorhexidine gluconate 4% followed by a 30 s application of isopropanol 70% and chlorhexidine gluconate 0.5%, and a 30 s application of isopropanol 70% and chlorhexidine gluconate 0.5% for consecutive scrubs (IPA); and (5) an initial scrub of 2 min with chlorhexidine gluconate 4% followed by a 30 s application of ethanol 70% and chlorhexidine gluconate 0.5%, and a 30 s application of ethanol 70% and chlorhexidine gluconate 0.5% for consecutive scrubs (EA). A convenience sample of 23 operating theatre nurses completed each scrub protocol for one week in a randomized order. A week of normal work activities intervened between each protocol. Subjects were assessed before commencing and after completing the week of each protocol to determine changes in the microbial counts and skin condition of the hands. Specimens for microbial analysis were collected before, immediately after and 2 h after an initial scrub, and 2 h after a consecutive scrub. The CHG-5, CHG-3 and PI-3 protocols, which used detergent-based antiseptics only, were compared with protocols incorporating an alcohol-based antiseptic (IPA and EA). The protocols incorporating alcohol-based antiseptics and the CHG-5 protocol were generally associated with the lowest post-scrub numbers of cfu.

RESULTS: No difference between the CHG-5 protocol and the alcohol-based antiseptics was found at the beginning of the test week, but after exclusive use of the respective protocols for a week, the alcohol-based antiseptics were associated with significantly lower cfu numbers in two out of the three post-scrub samples (P = 0.003, P = 0.035). Although virtually no statistically significant differences in skin condition were found, many subjects reported the alcohol-based antiseptic protocols to be less drying on the skin.

Reviewer's comments: The authors of this study support the proposition that a scrub protocol using alcohol-based antiseptics is as effective and no more damaging to skin than more time-consuming, conventional methods using detergent-based antiseptics. There was no information regarding blinding of the test materials and those analyzing the data. The ratio of males to females subjects were 5:27. There was no use of a baseline non-antimicrobial control soap. No description of neutralization validation was provided. Overall, the information gathered from this study focused mainly on comparing surgical hand disinfectants and the optimal scrub time. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Poon, C, Morgan, DJ, Pond, F, Kane, J, Tulloh BR. Studies of the surgical hand scrub. Aust NZ J Surg 1998;68:65-67.

This study was designed to evaluate the effectiveness of various scrub techniques in reducing bacterial skin flora.

DESIGN & METHODS: The study design was developed in three stages. Each stage involved fingertip bacterial colony counts measured before, immediately after and 30 minutes after a variety of handwashing techniques using 10% povidone iodine solution. The first compared 1, 2, or 3 non-timed washes from fingertips to elbows in 10 volunteers. The second compared two volunteers scrubbing for equal durations with or without friction rubbing, while the third involved 15 volunteers who each scrubbed for different time intervals. Volunteers rotated through each of the three techniques on separate days. Precise handwashing times were not recorded, but a single pass usually took between 20 and 45 seconds. A scrubbing brush was not used. After washing with disinfectant, volunteers dried their hands on a sterile cloth towel and then made fingertip impressions on an agar plate to provide the immediate post-scrub colony count. A sterile gown and gloves were then donned. After 30 minutes the gloves were removed and fingertip cultures were performed. The agar plates were then incubates at 37'C for 48 hours to colony counting by one individual who was blinded to the handwashing process.

RESULTS: There was considerable variation was seen in the pre-scrub colony counts between individuals and, to a lesser extent, for the same individual on different days. The organisms cultured were similar to those seen in other studies, and comprised mixed skin flora including coagulase-negative staphylococci, coliforms, and micrococci. The first stage showed that a single wash episode failed to provide lasting bacterial colony count reductions on fingertip cultures. The second showed that enduring colony count reductions occur whether friction rubbing of the hands was used or not, and the third showed that a 30 second wash was as effective as washing for longer periods in reducing fingertip flora.

Reviewer's Comments: Fingerprint technique method was used in this study. The authors conclude that prolong vigorous pre-operative scrubbing is unnecessary, although more than a cursory wash is required to produce lasting fingertip antisepsis. The study contained a small sample size of subjects. Demographics and disposition of the subjects were not provided. No washout period. The study was not blinded. This was not a clinical trial design study. Overall, the information gathered from this study focused mainly on scrub time. The study was not designed to demonstrate a correlation between infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Rehork, B and Ruden, H. "Investigations into the efficacy of different procedures for surgical hand disinfection between consecutive operations." J Hosp Infect 1991 (19):115-127.

In order to examine whether thorough surgical hand disinfection (handwashing plus hand disinfection) between consecutive operations is necessary, tests were carried out simulating normal clinical conditions.

DESIGN & METHODS: The tests were performed according to the guidelines for the evaluation of disinfection procedures of the German Society for Hygiene and Microbiology. Surgical hand disinfection was as follows: handwashing with soap without antimicrobial additives and subsequent 5-min disinfection with 60% n-propanol. This

was followed by simulated operations of 30 or 120 min duration with a 30-min break between operations, during which half of the test group kept on the surgical gloves, while the other half removed them. The second surgical hand disinfection was done without prior handwashing by 50% of the test group. The disinfection time was reduced from 5 to 1 min by 50% of the test group.

RESULTS: The results were evaluated by means of explorative data analysis and inductive statistical methods. Removing the surgical gloves during the interoperative break did not result in significantly higher numbers of colony forming units (cfu) compared with retaining the gloves. This was also the case after a subsequent handwashing. At the second surgical hand disinfection, after a simulated operation of 60 min duration (including break), there was no significant difference in the numbers of cfus between the test group who had washed their hands and those who had not. Reducing the disinfection time from 5 min to 1 min was not associated with a significant increase in the number of cfus. However, after a simulated operating time of 150 min (including the break), the second surgical hand disinfection with handwashing resulted in a significantly lower number of microorganisms than disinfection alone. In half the tests, the numbers of cfu were significantly lower when the test group disinfected their hands for 5 min rather than 1 min.

Reviewer's comments: The authors concluded that wearing surgical gloves during the interoperative break does not result in any microbiological advantages. The cfu numbers on the hands were not significantly lowered by wearing surgical gloves during the interoperative break. There were limitations in the study. Washout period was only for three days. Two weeks are required in the TFM. Demographics and disposition of the subjects were not provided. No description of whether subjects were using antibiotics and/or oral contraceptives (causes an adverse effect on the microbial flora of the skin) were included in the study. No description if neutralizers were used. There was no description of whether sampling was randomized. There was no valuable information regarding the correlation of infection rates to the reduction of bacteria. There was no clinical relevance depicted in the study.

Conclusion

Overall, based on the literature reviewed, the reviewers from the Healthcare Antiseptic Working Group found no evidence of a direct link between bacterial log reduction and decreased hospital infection rates pertaining the use of surgical hand scrubs. Most of the literature reviewed, have a number of confounding issues, such as lack of double blind controlled studies, randomizations, baseline recovery, statistical designs and analyses, various methods of surgical hand scrub technique methods, and use of neutralization. Additional research is needed to determine the appropriate surrogate endpoints to be used for surgical hand scrub drug products. However, the current endpoints established in the 1994 TFM criteria for surgical hand scrubs should remain standing until a valid clinical trial design is conducted. Currently the FDA has approved over 20 New Drug Applications (NDAs) based on the surrogate endpoints described in the TFM.

Michelle M. Jackson, Ph.D. Microbiology Reviewer Division of Over-the-Counter Drug Products

Concurrence:

John H. Powers, M.D. Medical Officer, Team Leader Office of Drug Evaluation IV

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Parienti JJ, Thibon P, Heller R, LeRoux Y, von Theobald P, Bensadoun H, Bouvet A, Lemarchand F, Le Coutour X. "Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates." JAMA 2002 (288):722-727.

Pereira, LJ, Lee, GM, and Wade, KJ. "An evaluation of five protocols for surgical handwashing in relation to skin condition and microbial counts." J Hosp Infect 1997 (36):49-65.

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Rehork, B and Ruden, H. "Investigations into the efficacy of different procedures for surgical hand disinfection between consecutive operations." J Hosp Infect 1991 (19):115-127.

APPENDIX I

- 1. ADA Division of Science on behalf of the ADA Council on Scientific Affairs. "Antiseptic antimicrobial hand washes." J Am Dent Assoc. 2003 Jul;134(7):906-7.
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